K073486

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## 510(K) SUMMARY

APR - 4 2008

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|---|---|
| 14-1. Submitter | Dentis Co. Ltd.<br>1-72 Woram-Dong, Dalseo-Gu, Daegu, Korea<br>Phone: 82-53-583-2804, Fax : 82-53-583-2806 |
| 14-2. US Agent / Contact Person | PhD. Chang Dae Kyu<br>13340 E. Firestone Blvd. Suite J<br>Santa Fe Springs, CA 90670<br>Phone : 562-404-8466, Fax : 562-404-2757 |
| 14-3. Date Prepared | December 07, 2007 |
| 14-4. Device Name | DENTIS DENTAL IMPLANT SYSTEMS<br>(Internal / External / Submerged Type) |
| 14-5. Classification Name | Endosseous Dental Implant System |
| 14-6. Device Classification | Class II<br>Dental Devices panel<br>21 CFR ξ 872.3640 |
| 14-7. Predicate Devices | SM® IMPLANT SYSTEMS(K061709)<br>E Z® IMPLANT SYSTEMS (070562) |
| 14-8. Performance | Laboratory testing was conducted to determine device functionality and conformance to design input requirements. |

14-9. Device Description

The Dentis Dental Implant System is comprised of dental implants, surgical instruments and prosthetic components. The system is designed for conventional two-stage for single and multiple unit prosthetics. The Dentis Dental Implant System consists of machined titanium, screw-form dental implant Ø 3.5mm, Ø 3.7mm, Ø 4.1mm, Ø 4.3mm, Ø 4.8mm, Ø 5.5mm, 6.0mm in diameter. They are available in length of 7-14 mm. The implant's raw material is titanium and its alloys for surgical implant applications (as per ASTM-F-67, ASTM-F-136). Surfaces include as machined surfaces, grit blasted and surfaces treated with Resorbable Blast Media (RBM) roughened surface.

The System includes surgical instruments such as twist drill, bone tap, Trephine

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12-10. Packing / Labeling / Product Information

In a clean room that is Class 10,000 or less, put the product into a capsule, and then put the capsule in a pet container, which is sealed the pet container with PERFECSEAL CR27 1073B Coated Tyvek®. Dentis Dental Implant Systems(Internal / External / Submerged Type Implant Fixtures, Protective Cap, and Implant System Surgery Tray) will be packaged.

12-11. Intended Use

The Dentis Dental Implant System is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four splinted interforminal placed implants, and not indicated for single, unsplinted implants. Patients must be subject for dental treatment with endosseous implants.

12-12. Substantial Equivalence Comparison

The Dentis Dental Implant system has a substantially equivalent intended use as the identified predicates.(K061797, K070562) All implants are intended for replacing missing teeth and supporting single or multiple-unit restorations in the mandible or maxilla. The Dentis Dental Implants are similar in fundamental scientific technology to the predicate devices(K061797, K070562) in that they are all threaded, root form implants constructed of titanium. The subject and predicate devices are similar in size and materials, are sterilized via gamma irradiation. The Dentis Dental Implant system and the predicates include instruments to assist with the implant procedure. When compared with the predicate devices, no new questions of safety or effectiveness have been raised for the Dental Implant System.

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This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR & 807.93

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 4 2008

Dentis Company, Limited
C/O Chang Dae Kyu Ph.D
U.S. Agent
Kodent, Incorporated
13340 East Firestone Boulevard, Suite J
Santa Fe Springs, California 90670

Re: K073486
Trade/Device Name: Dentis Dental Implant System
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: March 24, 2008
Received: March 24, 2008

Dear Dr. Kyu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

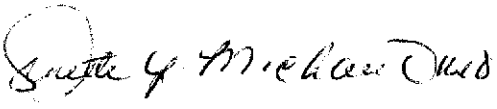
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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# Indication for Use

**510(K) Number (if known):** K073486

**Device Name:** Dentis Dental Implant System

**Indications For Use:**

The Dentis Dental Implant system is an endosseous dental implant that is indicated to use for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple units' prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading. Immediate loading is restricted to the anterior mandible, based on four splinted interforminal placed implants, and not indicated for single, unsplinted implants.

Prescription Use X AND/OR _____ Over – The-Counter Use

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073486